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COMMENTS OF THE TOBACCO INSTITUTE ON THE PETITION PROPOSING THE REGULATION OF CIGARETTE FILTERS AS MEDICAL DEVICES (Docket No. 78P-0338)

Action on Smoking and Health has filed a citizen petition with FDA requesting the agency to assert jurisdiction over cigarette filters under the Federal Food, Drug, and Cosmetic Act ("the Act") on the theory that they are "devices" as defined in the Act, and further requesting FDA to promulgate regulations governing the manufacture and distribution of cigarette filters. These comments on the petition are submitted pursuant to 21 C.F.R. § 10.30(d) by The Tobacco Institute, Inc., on behalf of all the country's manufacturers of cigarettes. The petition's argument that cigarette filters are medical devices is legally erroneous and should be rejected by FDA.

INTRODUCTION

The petition deals with "detached filter devices," as well as with filter cigarettes. As the petition itself notes (at pp. 5-6), detached filters are advertised and promoted differently from filter cigarettes. Detached filters are a type of product wholly different from filter cigarettes, sold by a different group of manufacturers, and with different

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labeling. These comments will address only the arguments made in the petition with respect to filter cigarettes.

As these comments will show, filters that are sold as part of filter cigarettes are not "devices" under the Federal Food, Drug, and Cosmetic Act. A product may be classified as a device only if its manufacturer represents it as useful in preventing or mitigating a disease, and such representations are not made for filter cigarettes. No health claims are made for filter cigarettes, and under the law, no determination that cigarette filters are devices can be based either on conjecture about purchasers' motivations or on manufacturers' disclosures concerning smoke components.

It will also be shown in these comments that any assertion by FDA of jurisdiction over cigarette filters would be unlawful because such regulation would conflict with federal legislation dealing specifically with cigarettes. This legislation makes clear the congressional intent that administrative agencies such as FDA are not to regulate cigarettes and specifically precludes use of the essential mechanisms by which FDA regulates medical devices.

I. Cigarette Filters Are Not Devices

Under clearly established law a product may be regulated as a medical device under the Federal Food, Drug, and Cosmetic Act only if the seller makes health claims

for the product. No such claims are made for filter cigarettes, nor can any such claims be inferred from cigarette advertising or from speculation about consumers' intentions. Accordingly, filter cigarettes are not subject to regulation as medical devices.

A. The Seller's Representations Determine Whether Cigarette Filters Are Devices.

Section 201(h) of the Act defines the term "device" to mean --

> An instrument, apparatus, implement, machine, contrivance, implant, in vitro reagent, or other similar or related article, including any component, part, or accessory, which is --
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> (1) recognized in the official National Formulary, or the United States Pharmacopeia, or any supplement to them,
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> (2) intended for use in the diagnosis of disease or other conditions, or in the cure, mitigation, treatment, or prevention of disease, in man or other animals, or
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> (3) intended to affect the structure or any function of the body of man or other animals, and
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> which does not achieve any of its principal intended purposes through chemical action within or on the body of man or other animals and which is not dependent upon being metabolized for the achievement of any of its principal intended purposes.

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While the petition asserts that certain detached filters are "intended to affect the structure or function of the body" because they are promoted as stop-smoking aids (p. 9), the petition's contention with respect to filter cigarettes is that they are "intended for use in the . . . mitigation . . . or prevention of disease."

Court decisions make clear that the "intended" uses of an article are determined by reference to the representations and claims that are made in its labeling, advertising, or other promotion. See, e.g., National Nutritional Foods Ass'n v. FDA, 504 F.2d 761, 789 (2d Cir. 1974), cert. denied, 420 U.S. 946 (1975); United States v. An Article . . . "Sudden Change," 409 F.2d 734, 739 (2d Cir. 1969); United States v. Article of Drug . . . B-Complex Cholinos Capsules, 362 F.2d 923 (3d Cir. 1966); Nature Food Centres, Inc. v. United States, 310 F.2d 67 (1st Cir. 1962), cert. denied, 371 U.S. 968 (1963); Action on Smoking and Health v. Califano, Civil Action No. 78-338 (D.D.C. Jan. 16, 1979); United States v. 46 Cartons . . . Fairfax Cigarettes, 113 F. Supp. 336 (D.N.J. 1953).

This legal principle was revised again in National Nutritional Foods Ass'n v. Mathews, 557 F.2d 325 (2d Cir. 1977), in which the court of appeals upheld a decision

invalidating an FDA regulation that had declared high-potency formulations of vitamins A and D to be "drugs" within the meaning of the Act without regard to their sellers' claims. FDA's theory was that these formulations were drugs because many persons in fact used them for therapeutic purposes. In rejecting this theory, the court said: "The vendors' intent in selling the product to the public is the key element in this statutory definition." */ 557 F.2d at 333.

Recently the U.S. District Court for the District of Columbia reaffirmed this rule with specific reference to cigarettes. In Action on Smoking and Health v. Califano, Civil Action No. 78-338 (Jan. 16, 1979), the court stated, "The 'intent' element of the definition of drug, when applied to cigarettes, has always been construed as that of the vendor . . . ." The court thus upheld FDA's determination that the seller's representations are dispositive. In the decision being reviewed, Commissioner Kennedy had stated:

> The petitioners have presented no evidence that manufacturers or vendors of cigarettes represent that the cigarettes are "intended to affect the structure or any function of the body of man . . ." 21 U.S.C. § 321(g)(1)(C).

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*/ So far as is relevant here, the definition of "drug" under the Act is identical to the "device" definition. Both definitions require that the article be "intended for use in the . . . mitigation . . . or prevention of disease." See § 201(b)(1)(B) and (h)(2) of the Act.

> Statements by the petitioners and citations in the petition that cigarettes are used by smokers to affect the structure or any functions of their bodies are not evidence of such intent by the manufacturers or vendors of cigarettes, as required under the provisions of 21 U.S.C § 321(g)(1)(C).*/

The teaching of these decisions, as acknowledged by FDA, is that a particular use may be considered to be a product's intended use only if the seller has affirmatively made representations that the product is suitable for such use. The courts' concern in these cases was not with the actual effects of the product or with the purchasers' intentions, but only with the sellers' claims.

This unanimous line of decisions is consistent with and, indeed, is required by the Act's legislative history. Congress intended to place the manufacturer in control of his product's regulatory status; only the manufacturer's claims were to be considered in ascertaining whether FDA had jurisdiction over the product:

> The manufacturer of the article, through his representations in connection with its sale, can determine the use to which the article is to be put. For example, the manufacturer of a laxative which is a medicated candy or chewing gum can bring his product within the definition of drug and escape that of food by representing

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*/ Letter from Donald Kennedy, Commissioner of Food and Drugs, to Mr. John F. Banzhaf, dated December 5, 1977.

> the article fairly and unequivocally as a drug product.

S. Rep. No. 361, 74th Cong., 1st Sess. 4 (1935).

In short, a clear principle has been established by the courts and the legislative history of the Act: The seller's representations are the basis for determining the intended use of a product.

B. Filter Cigarette Manufacturers Do Not Make Health Claims.

Health claims are not made for cigarette filters. Any review of cigarette labeling and advertising plainly reveals that filter cigarettes are being sold only for their taste, smoking enjoyment, and related characteristics. Manufacturers do not represent that filter cigarettes prevent or mitigate diseases. Since, as has been shown, a manufacturer's representations determine its product's status, the petition's contention that filter cigarettes are devices is erroneous.

The drafters of the petition were apparently aware of the paramount importance of the manufacturer's representations with respect to the regulatory status of a product since the petition struggles at length to find health claims in cigarette advertising. The petition concedes that no "outright" health claims are made (p. 11), but asserts that implied health claims can be found in advertisements. Even on the issue of

implied claims, however, the petitioner contends only that advertising "often" includes implied health claims (p. 10).

Analysis of the cigarette advertising submitted as part of the petition reveals no implied health claims. For example, the advertising campaign that calls a particular brand "the solution" is based, as the advertising copy reveals, on the new richer taste of the cigarette, not on any claim to medical benefits as the petition asserts. The advertisements describing the characteristics of filters do so without any implication of benefit to health, but solely in terms of their effect on tobacco smoke. The petitioner's difficulty in finding implied health claims in cigarette advertising is exemplified by its reliance on a 1975 advertisement (Ex. 5) and on advertisements of unknown vintage quoted in a 1971 book (p. 14 nn. 3-5).

At any rate, even if a few advertisements were determined to include implied health claims, that determination would apply only to the advertised cigarettes and not to other brands. The claims made by one vendor regarding a particular product may not be attributed to other vendors or to similar products. For example, it has been firmly established that drug claims made for one brand of cigarettes do not result in other brands of cigarettes being regarded as drugs. Compare Federal Trade Comm'n v. Liggett & Myers Tobacco Co., 108 F. Supp. 573, 575 (S.D.N.Y.

1952), aff'd 203 F.2d 955 (2d Cir. 1953), with United States v. 354 Bulk Cartons . . . Trim Reducing-Aid Cigarettes, 178 F. Supp. 847 (D.N.J. 1959). By the same token, advertisements making implied health claims for a particular brand cannot support the notion that filter cigarettes as a class are subject to regulation as devices.

In sum, there is no evidence whatever that filter cigarette manufacturers make representations that their products prevent or mitigate disease. Accordingly, filter cigarettes may not lawfully be classified as devices under the Act.

C. No Health Claim Can Be Inferred.

In apparent recognition of the fact that cigarette manufacturers do not make health claims for their products, the bulk of the petition is devoted to an argument that filter cigarettes should be regulated as medical devices on a basis other than the seller's representations. The petition contends that consumer intent, the beliefs of experts in the field of smoking and health, and the views of the FDA Anesthesiology Device Classification Panel are sufficient to subject filter cigarettes to regulation as medical devices.

In this regard, the petition relies heavily on dictum of the U.S. Court of Appeals for the Second Circuit,

which posited -- incorrectly, we believe -- an exception to the general rule that intended use is determined solely by a vendor's representations. In National Nutritional Foods Ass'n v. FDA, 504 F.2d 761, 788-89 (2d Cir. 1974), the court stated in effect that a substance could be presumed to be intended for drug use if it was in practice used "almost exclusively" for therapeutic purposes. See National Nutritional Foods Ass'n v. Mathews, 557 F.2d 325, 336 (2d Cir. 1977); National Nutritional Foods Ass'n v. Weinberger, 512 F.2d 688, 703 (2d Cir. 1975).

The court nevertheless invalidated FDA's attempt to classify as drugs all products containing more than specified amounts of vitamins and minerals, noting that "a significant number of persons have indisputable nutritional need for potencies exceeding the upper limits . . . ." 504 F.2d at 789. Therefore no assumption could be made that the products were being used almost exclusively for therapeutic purposes. As the court stated, "[T]he vendor of such a product can in good faith intend it for nontherapeutic use." Id.

Even if the exception apparently recognized (but not applied) in this case were correct, cigarette filters could not be presumed to be intended for a medical purpose. Filter cigarettes are sold and purchased for reasons having no relation to the mitigation or prevention of disease.

A primary motivation for the purchase of filter cigarettes is taste -- filter cigarettes are milder in taste than unfiltered cigarettes. The preference for filter cigarettes that has developed in recent years parallels the change in taste in other products. For example, the trend in sales of alcoholic beverages has been away from stronger tasting liquors, such as scotch and bourbon, toward lighter tasting (or tasteless) drinks, such as vodka and wines. Over the years, taste in coffee has similarly changed from stronger to lighter types. And tracking these trends in flavor preference have been analogous changes in other product lines -- such as increased desire for simplicity in design and the "natural look" in cosmetics. It is not surprising that these consumer tastes should be reflected in increased sales of milder tasting filter cigarettes and reduced consumption of stronger tasting unfiltered brands.

The esthetic advantage of filter cigarettes is undoubtedly also a factor to many consumers and has been since their introduction. A filter prevents tobacco particles from entering the smoker's mouth, which is a consideration many smokers find desirable.

Finally, the influence of fashion cannot be discounted. Some cigarette brands are more fashionable than others, and the filter plays a part in their appeal.

This same petitioner recently requested FDA to declare cigarettes to be drugs on the basis of consumer intent. The petitioner's allegations concerning consumer use there were similar to the assertions put forward in this petition with respect to filter cigarettes. FDA properly denied the petition, and the agency's action was upheld in Action on Smoking and Health v. Califano, supra, in which the court held that "we do not agree with plaintiff's contention that the Commissioner was obliged to . . . consider consumer use of cigarettes as evidence of its 'intended' use . . . " (slip. op. at 5). Evidence of consumer use "cannot amount to the objective evidence referred to in [National Nutritional Foods] that would 'pierce all of the manufacturer's subjective claims of intent'" (id.).

In short, even under the dictum in National Nutritional Foods, filter cigarettes are not devices. There has been no showing, nor could there be any showing, that filter cigarettes are used "almost exclusively" for safety or health reasons.

Whatever merit there is to the argument that consumer intent can be evidence of manufacturer intent, there is no legal basis for the strained extension advocated in the petition. The petition asserts that certain researchers are atempting to develop cigarette filters that prevent disease and that this is "objective evidence" that current filters have a similar purpose (Pet. at 26-28). The illogic in this conclusion is self-evident; the plans or expectations of

private researchers simply have no relevance to the intent of cigarette manufacturers.

The petition similarly attempts to rely on the recommendation of FDA's Anesthiology Device Classification Panel that "filters, tobacco smoke, attached" and "filters, tobacco smoke, unattached" be classified as Class III medical devises. While the Panel may be expert in assessing the safety and efficacy of medical devices (a task it did not undertake with respect to cigarette filters), it has no expertise on the legal question of whether a particular product is subject to regulation as a device. In comments previously filed with respect to the Panel's recommendation, The Tobacco Institute showed that the Panel's conclusion was legally in error.

D. Low "Tar" And Similar Claims Are Not Device Claims Under The Law.

The implied health claim the petition seeks to attribute to filter cigarette manufacturers is, apparently, that the removal of nicotine, "tar," or gases from tobacco smoke reduces the purported risk to smokers of contracting a smoking-related disease (Pet. 6). In this connection it is worthwhile pointing out that advertising focusing on the levels of "tar" and other components of cigarette smoke does not constitute health claims. That conclusion remains true

even when considered against the background of theories alleging a relationship between cigarette smoking and disease.

Moreover, as shown below a representation regarding the reduction of a smoke component cannot legally constitute a device claim. Indeed, such a representation would not be a device claim even if it were to be accompanied by an express statement relating the reduction to health effects.

Understanding the true nature of low "tar" or similar claim begins with an accurate definition of the product. The petitioner's argument that filter cigarettes should be regulated as medical devices rests analytically on the proposition that the cigarette filter is a product separate from the rest of the cigarette. In fact, however, cigarette manufacturers do not sell cigarette filters separately to the public. A cigarette, whether filtered or unfiltered, is an article designed to produce tobacco smoke, and the complete cigarette, not its separate components, is the product being marketed. Those manufacturers who emphasize the effectiveness of the filter or the "tar" content do so as a means of describing the tobacco smoke. The filter is merely one means to achieve this end, and not the product itself.

If tobacco is modified so as to produce low "tar" smoke without use of a filter, there would clearly be no argument that the cigarette was a medical device -- the petition's argument is based on the presence of an attached

filter. A difference in regulatory status based on whether or not a filter is used to achieve the "tar" reduction is plainly specious, however, because it is unrelated to the product actually being marketed -- an article for producing tobacco smoke.

Cnce it is recognized that filter cigarette manufacturers are selling cigarettes -- not filters -- it becomes obvious that representations related to the reduction of smoke components are not device claims. This conclusion follows from the legal distinction between claims about the presence in a product of an allegedly beneficial ingredient and claims about the absence or reduction of an allegedly deleterious ingredient. While FDA and the Federal Food, Drug, and Cosmetic Act recognize the possibility of drug or device claims arising out of the former, they do not recognize that possibility with respect to the latter. Removing an ingredient claimed by some to be harmful from a product and announcing its removal does not convert the product into a drug or device.

In the only judicial ruling on point, the court in Federal Trade Comm'n v. Liggett & Myers Tobacco Co., 108 F. Supp. 573, 575 (S.D.N.Y. 1952), aff'd 203 F.2d 955 (2d Cir. 1953), squarely held that representations about a product's lack of adverse effects are not therapeutic claims. That

action was brought by the FTC under the Federal Trade Commission Act, which in 15 U.S.C. § 55 incorporates the same definitions of "drug" and "device" as in the Federal Food, Drug, and Cosmetic Act. The court rejected the FTC's contention that certain cigarettes were drugs because they were represented as preventing irritation and having no adverse effect on smokers. 108 F. Supp. at 573, 575. Distinguishing earlier cases in which cigarettes claiming beneficial effects were determined to be drugs, the court held that a representation of a "non-adverse" effect did not make a cigarette a drug. 108 F. Supp. at 575.

Although FDA appears not to have articulated this principle expressly, its validity is evident from the agency's treatment of analogous claims. If a low "tar" representation for a cigarette is a health claim, then many widely made claims for foods would also be medical claims and would render the products drugs. For example, various diseases have been linked to sugar, cholesterol, sodium, and obesity, but foods promoted as low in sugar, cholesterol, sodium, fat, or calories, are not regarded as drugs by FDA.*/ As another example, "contains no

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*/ One must recognize the distinction between, on the one hand, unproven and hence potentially misleading claims and, on the other hand, drug or device claims. FDA limits the nature of a low-cholesterol claim to a specific format (21 C.F.R. § 101.25) because of the lack of an established connection between cholesterol and disease, but there is no suggestion that a low-cholesterol claim makes the food into a drug.

preservatives or other additives" is not regarded as a drug claim despite the implication that additives and preservatives are bad for one's health. If filter cigarettes are devices because of low "tar" claims, then all these products would be drugs.

A manufacturer may not only claim reduction or elimination of a deleterious ingredient without rendering the product a drug or device, it may also explicitly identify the hazard associated with the deleted ingredient.

Thus, for example, a food product could be labeled "Contains no saccharin -- which has been found to cause cancer in laboratory animals and may be hazardous to your health," without transforming the product into a drug. Without becoming a drug, a product could claim to be free of fluorocarbon propellants and note that such products may harm the ozone layer and accordingly human health. Labeling of a sugar-free chewing gum may, without making the product a drug, refer to the link between sugar and dental caries and assert that the product "does not promote tooth decay." A reduced calorie food product could describe the medical dangers associated with obesity without becoming a drug.

FDA regulations have recognized the examples of hypoallergenic foods and cosmetics (21 C.F.R. §§ 105.62, 701.100).*/ Under these regulations a food or cosmetic may explicitly represent that it is less likely to cause an allergic reaction because certain ingredients are not present. Such a representation does not, however, make the product a drug.

Applying these principles to cigarettes, it is indisputable that low "tar" and other claims related to reduction of smoke components are not representations that would make cigarettes devices. Since, as shown above, explicit statements can be made about the consequences of eliminating ingredients without rendering them drugs or devices, it is clear a fortiori that a filter cigarette is not a device based on the asserted implications in advertisements adduced by the petitioner.

E. The Consequences Of Regulating Filter Cigarettes As Devices Demonstrate That The Device Law Was Not Intended To Apply To Them.

If cigarette filters are declared to be devices on the theory that they are being offered for the prevention or mitigation of disease, the Act requires a demonstration

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*/ The regulation on hypoallergenic cosmetics was recently invalidated by a court for reasons unrelated to the point. See 43 Fed. Reg. 10559 (Mar. 14, 1978).

that the filters are effective for their intended use. It has not been shown, however, that "tar," or any component as found in tobacco smoke, causes disease, nor have any hazards been established for various levels of such substances.

As a result, filter cigarette manufacturers would be unable to meet the burden of proof imposed on device manufacturers, and FDA would evidently be obliged to ban filter cigarettes. The public interest would plainly not be served by such action. Smokers would be denied the milder taste and other advantages of filter cigarettes, and the outcry from consumers would undoubtedly be substantial. All would rightly wonder how the public interest was being served by an FDA ban on filter cigarettes (and only filter cigarettes). Interpreting a regulatory statute so as to result in a ban that would be universally perceived as misguided and irresponsible further proves that, as matters of good logic, common sense, practical dictates of the marketplace, and public policy, cigarette filters were not meant to be regulated as medical devices.

Even if a ban were avoided, regulating filter cigarettes as devices could unnecessarily stultify the development of new types of filters by subjecting them to lengthy and costly clearance procedures involving difficult or insurmountable burdens of proof. Such obstacles would be raised by legislation designed to further the public health although, in the context

of filter cigarettes, compliance with the Act's requirement cannot possibly benefit the public health. This paradox demonstrates the irrationality of attempting to regulate filter cigarettes as devices. Filter cigarettes do not satisfy the definition of a device; it would be senseless to regulate them as devices.

F. Petitioner's Authorities Are Unpersuasive.

The petition opens with an appeal for an expansive reading of the Act's jurisdictional provisions and cites United States v. An Article of Drug . . . Bacto-Unidisk, 394 U.S. 784 (1969), and the Medical Device Amendments of 1976 in support of this argument. Bacto-Unidisk, however, did not deal with the question, as does the petition, of whether the Act should be read broadly for the purpose of reaching products not previously regarded as subject to the Act. The question in that case was whether a product conceded to be within FDA's jurisdiction should be regulated as a "drug" or as a "device." Moreover, the Supreme Court cautioned in Bacto-Unidisk that "in our anxiety to effectuate the congressional purpose of protecting the public, we must take care not to extend the scope of the statute beyond the point where Congress indicated it would stop." 394 U.S. at 800. As we have shown, it is precisely such an extension that would be required to subject filter cigarettes to FDA jurisdiction.

The petition's reliance on the 1976 Amendments as supporting an expansive view of FDA's jurisdiction is similarly misplaced. The 1976 change in the definition of "device" merely codified the result in Bacto-Unidisk and did not seek to subject previously unregulated products to FDA's jurisdiction. In short, there is no basis for presuming broad FDA jurisdiction, and the Act's applicability to particular products must be determined in the light of statutory language and congressional intent. As we have shown, the statutory language and legislative history, as well as a consistent line of judicial and administrative precedent, demonstrate that filter cigarettes are not devices under the Act.

II. FDA Regulation Of Cigarette Filters Would Conflict With Federal Legislation Dealing Specifically With Cigarettes

In legislation enacted in 1965 and 1969, Congress established a comprehensive program to deal with smoking and health issues and reserved for itself the exclusive authority to formulate policies concerning the labeling, advertising, and sale of cigarettes.*/ Assumption of regulatory authority over cigarette filters by FDA would necessarily bring the agency into conflict with the preemptive purpose of these Acts.

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*/ 15 U.S.C. §§ 1331-1340.

A. Congress Has Preempted The Field Of Smoking And Health Regulation.

The express provisions and legislative history of the Cigarette Acts of 1965 and 1969 make clear Congress' intent to preclude FDA and other federal administrative agencies from requiring health-related labeling different from that required by the Acts. In addition, those Acts make clear the congressional intent to preclude any agency from prohibiting or restricting the sale of cigarettes.

When it adopted the two Cigarette Acts, Congress sought to balance the complex interests involved in the smoking and health controversy. That balance was reflected in the statute itself, which stated that its purpose was:

> [T]o establish a comprehensive Federal program to deal with cigarette labeling and advertising with respect to any relationship between smoking and health, whereby --
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> (1) the public may be adequately informed that cigarette smoking may be hazardous to health by inclusion of a warning to that effect on each package of cigarettes; and
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> (2) commerce and the national economy may be (A) protected to the maximum extent consistent with this declared policy and (B) not impeded by diverse, nonuniform, and confusing cigarette labeling and advertising regulations with respect to any relationship between smoking and health. */

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*/ 15 U.S.C. § 1331.

Congress decided in 1965 that the continued sale and advertisement of cigarettes should be permitted, but directed manufacturers to provide a prescribed warning to the smoking public concerning the asserted health hazards of smoking. The Cigarette Labeling and Advertising Act of 1965 spelled out the health-related statement to be required on all cigarette packages, and the Act prohibited all other health-related labeling:

> No statement relating to smoking and health, other than the statement required by Section 1333 of this title, shall be required on any cigarette package. */

Congressional preemption of the field of smoking and health was not limited to questions of labeling and advertising. Congress retained for itself the sole authority to make regulatory policy in the area, including the power to decide whether the sale of cigarettes should be restricted.

This preemptive intent has been clearly recognized by FDA in the past. In 1972 congressional hearings, for example, FDA Commissioner Charles C. Edwards stated:

> Congress has clearly enunciated its policy on cigarettes in section 2 of the Public Health Cigarette Smoking Act. This provides that the public should be adequately informed about the hazards of smoking and that commerce and the national economy should be protected to the maximum extent consistent with this declared policy . . . .

> This Act also we believe demonstrates that the regulation of cigarettes is to be the domain of Congress. No statement relating to smoking and health can be required on cigarettes except the warning prescribed by Congress.
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> In sum, labeling or banning cigarettes is a step that can be taken only by the Congress. Any such move by FDA would be inconsistent with the clear congressional intent. */

Commissioner Edwards' statement rested on a solid foundation. The 1965 and 1969 Acts reflect the intent of Congress as to how cigarettes are to be marketed. A stated purpose of the Acts is "to establish a comprehensive Federal program to deal with cigarette labeling and advertising with respect to any relationship between smoking and health." **/ In addition, the Acts demonstrate a determination that cigarettes shall be marketed, and that Congress alone will decide what restrictions, if any, will be placed on their sale. The Cigarette Acts direct HEW and FTC to submit annual reports on smoking questions with "recommendations for legislation." ***/ But,

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*/ Hearings on the Public Health Cigarette Amendments of 1971 Before the Consumer Subcommittee of the Senate Commerce Committee, 92d Cong., 2d Sess. 242 (1972).

**/ 15 U.S.C. § 1331.

***/ 15 U.S.C. §§ 1337(a), (b).

as the House Interstate and Foreign Commerce Committee stated in its report on the 1965 Act:

> The determination of appropriate remedial action in this area . . . is a responsibility which should be exercised by the Congress after considering all facets of the problem.*/

The appropriateness of FDA's deference to Congress in this area was recognized by the court in Action on Smoking and Health v. Califano, supra. The court observed there that the agency's refusal to regulate cigarettes as drugs was "of course" based on its "perception of congressional intent with regard to the regulation of cigarettes" (slip op. at 4), and further stated that "[i]t is not necessary to advert to the fact that Congress despite numerous opportunities, has never challenged defendants' interpretation of the Act as it affects its jurisdiction over cigarettes or nicotine as 'drugs'" (slip op. at 6 n.4).

B. Regulation Of Cigarette Filters As Medical Devices Would Necessarily Conflict With The Cigarette Acts.

The petition is careful not to recommend any specific form of regulation for filter cigarettes, asserting

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*/ H.R. Rep. No. 449, 89th Cong., 1st Sess. 3 (1965).

that "[s]uch a determination is best made as part of a rulemaking proceeding" (Pet. 31). The probable reason for such an approach is that the impracticability and illegality of the petition's proposal would become obvious once reduced from abstract generality to a specific regulatory program. There are basically only two kinds of action open to FDA if it determines that cigarette filters are devices. It can prohibit some or all filters, or it can require certain labeling concerning the filters. */ Neither type of action would, however, be permissible under the 1965 and 1969 Cigarette Acts.

1. The Standard Setting Authority For Devices Could Not Be Enforced.

The essential feature of device regulation under the Federal Food, Drug, and Cosmetic Act is the statutory prohibition on the sale of devices that FDA determines have not been proved safe and effective. Thus, if FDA were to regulate cigarette filters as devices, the agency would

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*/ FDA also has authority over minor aspects of production and marketing such as sanitation, but these controls are collateral to the basic purposes of device regulation.

prohibit those filters that did not meet its established criteria.*/

In the case of filter cigarettes, however, it is impossible to ban a filter without also banning the cigarette. A filter cigarette is developed as a unit. Substitution of the filter with a different kind would change the taste and other characteristics of the cigarette, and the resulting cigarette would not be the same as the one previously marketed.

Any FDA required change in the composition of a filter cigarette would plainly be inconsistent with the Cigarette Acts, which determined that cigarettes should continue to be marketed. An FDA imposed reformulation of filter cigarettes would certainly damage the sales of the brands affected and could seriously disrupt all cigarette marketing, since approximately 90 percent of the cigarettes sold in the country have filters attached. FDA action that reduced sales of some or all cigarette brands would amount to a restriction of the kind prohibited by Congress.

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*/ The criteria would vary in form depending on whether FDA regulated cigarette filters through premarketing approval, performance standards, or general postmarketing controls, but the result in any case would be the same.

The congressional intention that administrative agencies not tamper with cigarettes in a way that might affect their marketing has been repeatedly evidenced. Discussing proposals by the FCC to ban cigarette advertising in broadcast media and the FTC to require health warnings in print advertising for cigarettes, the House Interstate and Foreign Commerce Committee said in its report on the 1969 Act:

> It is obvious that if [the proposed] regulations are allowed to go into effect . . . they would have an impact on areas far beyond those intended by the Congress to be regulated by these agencies. The regulations . . . would affect the growing, sale, and manufacturing of tobacco for cigarettes and the persons involved in or affected by those activities.
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> These activities cut across the whole spectrum of commercial and social life in the United States. It is therefore an area where the Congress, if anyone, must make policy.
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> Aside from the questions of constitutional and statutory law which the two agencies' proposed rules raise, they are an assumption by these agencies of policymaking with respect to a subject matter on which the Congress has made policy (see section 5(b) of the Act), has stated its intention to be the exclusive policymaker on the subject matter, at least until July 1, 1969 (see section 10 of the Act), and has given strong indication of its intention to continue to do so.

> Therefore, the Committee feels it is incumbent on the Congress to act on the reported legislation in order to prevent intrusion by the Federal Communications Commission and the Federal Trade Commission into basic areas of policymaking which it has reserved to itself.*/

Congress enacted the proposed legislation as the Public Health Cigarette Smoking Act of 1969.

In its unpublished opinion in American Public Health Association v. Consumer Product Safety Comm'n, C.A. No. 74-1222 (D.D.C. April 23, 1975), the district court disregarded these clear congressional directives and determined that the Consumer Product Safety Commission could lawfully exercise jurisdiction over cigarettes under the Federal Hazardous Substances Act to impose cautionary label statements different from those specified by Congress or to ban entirely the sale

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*/ H.R. Rep. No. 91-289, 91st Cong., 1st Sess. at 4-5 (1969) (emphasis added).

of high-tar cigarettes.*/

Congressional response to the APHA decision was rapid and explicit. On June 24, 1975, the Senate Commerce Committee and the House Committee on Interstate and Foreign Commerce reported bills that eliminated CPSC's authority to regulate cigarette labeling or to ban cigarettes under the FHSA.**/ The bill reported to the House simply eliminated tobacco and tobacco products from the coverage of the FHSA. The Senate committee's bill permitted CPSC to retain jurisdiction over tobacco products as an "ignition source." Five of the Senate committee members objected to this limited grant of authority, stating that:

> The Consumer Product Safety Commission lacks the expertise and the resources to deal with this question. It does not have the competence to make critical judgments as to the relationship between burning rates of tobacco products and necessarily intertwined and paramountly important questions relating to the components of cigarette smoke. These are all aspects of the basic regulation of tobacco products, particularly cigarettes, which Congress has retained for final decision,

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*/ The district court's decision was never tested on appeal, but was vacated as moot when Congress repudiated its holding. The decision, which contravenes the plain language of the preemptive provisions of the cigarette acts and the clear legislative intent to reserve the field of smoking and health for congressional policymaking, is not entitled to serious consideration. It should not govern the determination whether cigarette filters may be regulated under the Federal Food, Drug, and Cosmetic Act.

**/ S. Rep. No. 94-251, 94th Cong., 1st Sess. (1975); H.R. Rep. No. 94-325, 94th Cong., 1st Sess. (1975).

> based on input from all agencies of the government. The Congress, being the only body in a position to evaluate all pertinent factors, should continue its fully-considered policy of retaining final authority on this area.*/

In the end, this position prevailed. The Conference Committee deleted the provisions granting the Commission authority over cigarettes as an ignition source,**/ and Congress enacted a statute that eliminated all CPSC authority to regulate cigarettes.

Just as Congress saw the issue of cigarettes as ignition sources inextricably tied to cigarette policy as a whole, so also would it view the regulation of cigarette filters as intertwined with national policy on tobacco products. An FDA ban on certain filters would bring the agency squarely into conflict with the preemptive purpose of the Cigarette Acts.

2. FDA Could Not Require Filter Cigarettes To Be Labeled As Devices.

The Cigarette Acts not only preempt FDA's authority to approve and disapprove specific filters, they also preempt FDA's authority to require the labeling that would be necessary if filters were regulated as devices.

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*/ S. Rep. No. 94-251, 94th Cong., 1st Sess. 45 (1975) (emphasis added).

**/ H.R. Rep. No. 94-1022, 94th Cong., 2d Sess. 16 (1976),

Under Section 502(f) of the Act, a device must bear "adequate directions for use." FDA regulations define "adequate directions for use" for a device as including "statements of all conditions, purposes, or uses for which such device is intended, including conditions, purposes or uses for which it is prescribed, recommended, or suggested . . . ." 21 C.F.R. § 801.5(a). It is clear from this regulation -- and from the law generally -- that filter cigarette labeling would have to include a statement of the filter's indicated use if the filter is a device. But any such statement would necessarily constitute a statement about smoking and health, which is expressly prohibited by the 1965 and 1969 Cigarette Acts.*/

The regulatory scheme for medical devices is wholly inappropriate for products for which FDA cannot regulate the labeling claims. The scheme depends entirely on FDA's determining the accuracy of claimed benefits and limiting label claims to those benefits -- an impossibility where FDA cannot regulate the labeling. Moreover, the labeling information is not limited

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*/ "No statement relating to smoking and health, other than the statement required by Section 1333 of this title, shall be required on any cigarette package." 15 U.S.C. § 1334(a).

to a general statement of a device's indicated use. Very specific language may be necessary to distinguish among similar devices of varying effectiveness. If, for example, the X device prevents seven different diseases while the similar Y device mitigates only one, that difference must be communicated in labeling if the regulatory scheme is to be meaningful. But in the case of cigarettes absolutely no health related labeling could be required, and the statutory plan for regulating medical devices therefore cannot be implemented.

In summary, the Cigarette Acts would prevent FDA both from banning types of filter cigarettes and from requiring labeling related to health benefits. With these essential elements of medical device regulation preempted, it is obvious that Congress did not intend for cigarette filters to be regulated as devices.

CONCLUSION

We have shown in these comments that cigarette filters are not "devices" within the meaning of the Federal Food, Drug, and Cosmetic Act. A product can be regulated as a medical device only on the basis of the manufacturer's health claims, and filter cigarette manufacturers simply do not make such claims. Moreover, regulation of filter cigarettes as devices is precluded by statutes regulating cigarettes that preempt action by federal agencies of the sort urged on FDA in

this proceeding. FDA has no authority to regulate filter cigarettes, and it should deny the petition.

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